

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH,

Plaintiff,

Civil Action No. 06-222 (JJF)

v.

PUBLIC VERSION

IMPAX LABORATORIES, INC.,

Defendant.

**SUPPLEMENTAL BRIEF IN SUPPORT OF
IMPAX LABORATORIES' OPPOSITION TO WYETH'S
MOTION TO STRIKE THE EXPERT REPORT OF MARK E. NUSBAUM**

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I. INTRODUCTION

During the November 9, 2007 hearing on Wyeth's Motion to Strike, the Court directed Impax to file a supplemental brief explaining "what Mr. Nusbaum would put into the record" relating to "any appeal that might be necessitated by an adverse ruling to [Impax] at trial." (11/9/07 Tr. at 5-6). The Court should deny Wyeth's Motion to Strike because Mr. Nusbaum will introduce testimony relevant to Wyeth's inequitable conduct, which the Federal Circuit would consider on appeal. As a former Examiner-in Chief of the PTO, Mr. Nusbaum is the only Impax witness who will be able to explain to the Court—and to the Federal Circuit if an appeal is necessary—why Wyeth's failure to disclose relevant information to the PTO would have been material to a reasonable patent examiner.

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Moreover, unlike any other expert who would be bound by the actual claim construction of the patents-in-suit, Mr. Nusbaum would be testifying about what would be material to a patent examiner who would be required to view the claims using the broadest reasonable interpretation consistent with the specification. Indeed, in reviewing a district court's determination on inequitable conduct, the Federal Circuit often relies on the testimony of experts—like Mr. Nusbaum—when deciding whether the district court has abused its discretion. Accordingly, the Court should deny Wyeth's Motion to Strike.

II. ARGUMENT

Impax contends that Wyeth engaged in inequitable conduct by failing to disclose material information to the PTO prior to obtaining U.S. Patent Nos. 6,274,171 B1 ("171 patent") 6,403,120 B1 ("120 patent") and 6,419,958 B2 ("958 patent"). The Federal Circuit considers expert testimony when evaluating whether inequitable conduct has occurred. *See McKesson*

Info. Solutions, Inc. v. Bridge Med., Inc., 487 F.3d 897, 908 (Fed. Cir. 2007); *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1238 (Fed. Cir. 2003); *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988). Importantly, the failure to provide expert testimony on inequitable conduct can lead to denial of a defendant's appeal on that issue. *See Bristol-Myers Squibb Co.*, 326 F.3d at 1238 ("To the extent that the opinion of the inventors as to how a reasonable examiner would have viewed the article sheds light on materiality, the district court did not find the testimony persuasive because it was 'the self-serving testimony of an interested witness' and was supported by neither objective evidence nor by the testimony of any independent expert."). The Federal Circuit reviews a district court's underlying factual findings of materiality and intent for clear error and the ultimate inequitable conduct determination for an abuse of discretion. *Frazier v. Roessel Cine Photo Tech, Inc.*, 417 F.3d 1230, 1234 (Fed. Cir. 2005).

A patent may be rendered unenforceable for inequitable conduct "if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the PTO during prosecution." *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006). The materiality of information withheld during prosecution is judged under the "reasonable examiner" standard. *See id.* at 1316. That is, "[m]ateriality . . . embraces any information that a reasonable examiner would substantially likely consider important in deciding whether to allow an application to issue as a patent." *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F. 3d 1380, 1382 (Fed. Cir. 1998) (citations omitted). Moreover, "[i]nformation concealed from the PTO may be material even though it would not invalidate the patent." *Li Second Family L.P. v. Toshiba Corp.*, 231 F.3d 1373, 1380 (Fed. Cir. 2000). Thus, information can be material to a reasonable patent examiner, and lead to unenforceability for inequitable conduct, even if it would not have prevented the

patent from issuing. *See PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F. 3d 1315, 1322 (Fed. Cir. 2000).

When evaluating whether material should be disclosed to the examiner, reviewing courts must bear in mind that “[c]lose cases should be resolved by disclosure, not unilaterally by the applicant.” *LaBounty Mfg. v. ITC*, 958 F.2d 1066, 1076 (Fed. Cir. 1992). Accordingly, when assessing materiality from the perspective of a reasonable patent examiner, reviewing courts must give claim language its broadest reasonable interpretation consistent with the specification. *See Exxon Research & Engineering Co. v. United States*, 265 F. 3d 1371, 1380 (Fed. Cir. 2001); *In re Yamamoto*, 740 F. 2d 1569, 1571, (Fed. Cir. 1984).

Here, Impax will show that Wyeth engaged in inequitable conduct by failing to provide the PTO with material information. Only Mr. Nusbaum—as a former Examiner-in Chief at the PTO and member of the Board of Patent Appeals and Interferences—can testify as to what a reasonable patent examiner would have deemed material. He will testify that a reasonable patent examiner would have deemed material Wyeth’s failure to disclose information inconsistent with Wyeth’s assertions of patentability. *See* Declaration of Mary Matterer in Support of Impax’s Opposition to Wyeth’s Motion to Strike (“Matterer Decl.”), Ex. 2 (Supplemental Expert Report of Mark E. Nusbaum) at ¶89. The Federal Circuit will consider Mr. Nusbaum’s testimony when evaluating whether or not the district court abused its discretion in ruling on Impax’s inequitable conduct defense. *See Bristol-Myers Squibb Co.*, 326 F.3d at 1238. Accordingly, to preserve Impax’s rights to meaningful appellate review, this Court should deny Wyeth’s Motion to Strike Mr. Nusbaum’s testimony.

- A. Mr. Nusbaum’s testimony is necessary to show that Wyeth failed to disclose relevant data about its clinical studies.**

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this Court were to conclude otherwise, and this action were to be appealed, Impax would rely on Mr. Nusbaum's testimony to explain why a reasonable patent examiner would have deemed material **REDACTED** The Federal Circuit then would

review that testimony in determining whether this Court erred in evaluating the materiality of these studies. While other Impax experts can testify as to what prior art should have been disclosed to the PTO, Accordingly, only an expert

REDACTED qualified to explain what a reasonable patent examiner would have deemed to be material can testify **REDACTED** Thus, Mr. Nusbaum's

testimony would allow Impax to create a complete evidentiary record of Wyeth's inequitable conduct for appeal.

Specifically, Mr. Nusbaum would testify as to why Wyeth should have disclosed

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In addition, Mr. Nusbaum would testify that the patent examiner should have been given

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Mr. Nusbaum would testify that

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Unless the Court permits Mr. Nusbaum to testify, Impax will not have an expert to explain

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Mr. Nusbaum's testimony could form the basis of the Federal Circuit's decision to either affirm or overturn the Court's findings on materiality and inequitable conduct. Without Mr. Nusbaum, Impax will not be able to present a full evidentiary record regarding why Wyeth's misrepresentations about this information would have been material to a reasonable patent examiner. Because the Federal Circuit—in evaluating this Court's findings—may ultimately determine that Impax has not met its burden of demonstrating inequitable conduct if Mr. Nusbaum is excluded from trial, *see Bristol-Myers Squibb Co.*, 326 F.3d at 1238, the Court should deny Wyeth's Motion to Strike.

B. Mr. Nusbaum's testimony is necessary to demonstrate that a reasonable patent examiner would have found material Wyeth's failure to disclose information relating to the Alza PCT application.

Mr. Nusbaum will also testify regarding why a reasonable patent examiner would have deemed material Wyeth's failure to disclose

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That is because unlike any other expert who must evaluate what is prior art in light of the actual scope of the claims, Mr. Nusbaum will evaluate materiality from the perspective of a reasonable patent examiner giving the claim language a much broader interpretation. *Id.*

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Mr. Nusbaum will testify that a reasonable examiner would have found such information to be material because it

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III. CONCLUSION

Because Mr. Nusbaum is the only Impax witness who can testify regarding the materiality of this information to the PTO, the Court should permit him to testify at trial. If the Court were to rule against Impax on the inequitable conduct claim, Mr. Nusbaum's testimony would be helpful to the Federal Circuit's review of whether the Court abused its discretion. Indeed, the Federal Circuit routinely reviews expert testimony on inequitable conduct when evaluating district court findings. If this Court excludes Mr. Nusbaum's testimony, Impax will be precluded from making a full evidentiary case under Federal Circuit precedent. *See Bristol-Myers Squibb Co.*, 326 F.3d at 1238. The Court should deny Wyeth's untimely and inappropriate Motion to Strike Mr. Nusbaum's expert report,¹ and permit Mr. Nusbaum to testify at trial.

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¹ For the reasons stated in Impax's prior briefs, Wyeth's Motion to Strike should be denied in its entirety. In any event, final resolution of which portions are admissible and which are not should be reserved for trial or pre-trial motions. *See Chamberlain Group, Inc. v. Interlogix, Inc.*, 2002 U.S. Dist. Lexis 6998, *4 (N.D. Ill. April 18, 2002).